p-Menthane-3,8-diol (PMD)
(PC Code: 011550)

Preliminary Work Plan and Summary Document

Registration Review: Initial Docket

December, 2015

Case # 6017

Approved by:

Robert McNally, Director
Biopesticides and
Pollution Prevention Division

Date:

12/17/15

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

BPPD	The EPA's Biopesticides and Pollution Prevention Division
C.F.R.	Code of Federal Regulations
DCI	Data call-in
EDSP	Endocrine Disruptor Screening Program
EPA	U.S. Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
FWP	Final Work Plan
IDS	Incident Data System
MRID No.	Master Record Identification Number: The EPA's system of recording and tracking studies submitted to the Office of Pesticide Programs.
MRL	Maximum Residue Limit
OPP	The EPA's Office of Pesticide Programs
PC Code	Pesticide chemical code: a six-digit number assigned by OPP to identify pesticide chemicals.
PMRA	Health Canada's Pest Management Regulatory Agency
PWP	Preliminary Work Plan
TGAI	Technical grade of the active ingredient
TMDL	Total Maximum Daily Load
U.S.	United States

I. PRELIMINARY WORK PLAN

A. Overview

The docket for p-Menthane-3,8-diol (PMD) is now open, initiating the first public comment period for registration review case #6017 (docket number EPA-HQ-OPP-2015-0693). PMD is registered for use as an insect repellent to be applied to exposed human skin and clothing. This preliminary work plan (PWP) explains what the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) knows about PMD, highlighting anticipated data and assessment needs, identifies types of information that would be especially useful to the EPA in conducting the review, and provides an anticipated timeline for completing review of PMD.

The registration review process was designed to include a public participation component to solicit input from interested stakeholders. The EPA intends, by sharing this information in the docket, to inform the public of what it knows about PMD, and what types of new data or other information would be helpful for the Agency to receive as it moves toward a decision on PMD. The EPA encourages all interested stakeholders to review the PWP and to provide comments and additional information that will help the EPA's decision-making process for this biochemical pesticide. In addition to general areas on which persons may wish to comment, there are some areas identified in the PWP about which the EPA specifically seeks comments and information. Interested stakeholders could include the following: environmental nonprofit or interest groups; pesticide manufacturers; agricultural labor or commodity groups; commercial, institutional, residential, and other users of pesticides; or the public at large.

The PWP begins by discussing the statutory and regulatory authority for registration review. Next, it provides background on PMD, which includes a description of its mode of action, currently registered pesticide products, application rates and methods, use sites, and tolerance exemption information. Then, it lists the anticipated data needs and risk assessments and a projected registration review timeline for PMD. Finally, the PWP describes guidance for commenters, explains the next steps EPA will be taking, summarizes background information, and lists supporting studies, risk assessment memoranda, and other documents.

Further information about this case, including background and supporting documents, is available at *http://www.regulations.gov* (under "SEARCH for: Rules, Comments, Adjudications or Supporting Documents," enter the docket identification number, which is indicated above).

B. Statutory and Regulatory Authority

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the EPA, based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on the product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure

that as changes occur, products in the marketplace are safe to use. Information on this program is provided on the EPA's website.[1]

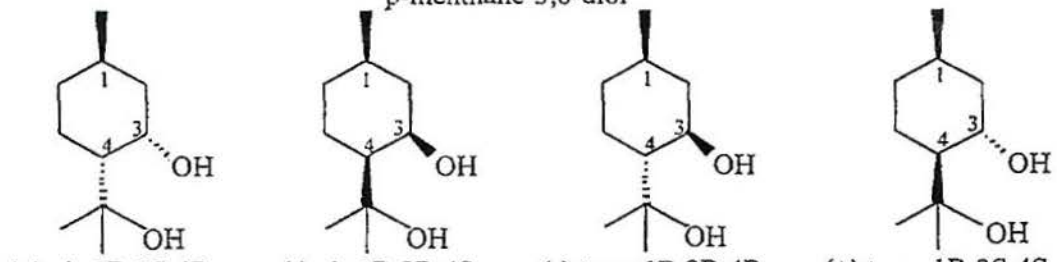
The Agency is implementing the registration review program pursuant to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(g), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 C.F.R. § 155.40. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the EPA will develop a final work plan (FWP) and anticipated schedule for the registration review of PMD.

C. Background and Regulatory Information

i. Summary of the Active Ingredient and the Associated Pesticide Products.

PMD (*p*-menthane-3,8-diol) is chemically synthesized for commercial use as an active ingredient in topical repellent products. It is commonly referred to as oil of lemon eucalyptus, because it is derived from leaves and twigs of eucalyptus plants, and is structurally similar to menthol. Although both names are used interchangeably when used as insect repellents, PMD and pure, unrefined oil of lemon eucalyptus are chemically distinct. The empirical formula of PMD is $C_{10}H_{20}O_2$, and its structural formula is:

p-menthane-3,8-diol



(+) cis 1R;3S;4R (-) cis 1R;3R;4S (-) trans 1R;3R;4R (+) trans 1R;3S;4S

Other chemical names include Cyclohexanemethanol, 2-hydroxy-alpha, and alpha, 4-trimethyl. The PMD technical, formerly called Granola 97, was first submitted for registration in the USA on November 28, 1997, by S.C. Johnson & Son, Inc. It was registered as a Manufacturing-Use Product (MUP) on March 31, 2000, for use in repellent products intended to repel insects of human health significance, such as mosquitoes, biting flies and gnats. The technical grade active ingredient is formulated as 99% PMD. The mode of action of PMD is non-toxic. The specific mechanism of

[1] See http://www.epa.gov/oppsrrd1/registration_review/

repellency is unknown, but it is believed that PMD interferes with host-finding mechanism of blood-feeding arthropods. Blood–sucking insects rely on sensory receptors to locate their hosts, and are attracted to several cues emitted by their host, such as carbon dioxide, lactic acid, body heat, humidity, ammonia, and phenols. PMD interferes with the arthropods' ability to locate their host by masking these cues. Tables 1 and 2 provide a summary of the chemical facts, use and usage information for PMD.

Table 1. Chemical Facts for PMD

PC code	011550
Case Number	6017
CAS Number	42822-86-6
Year first registered	March 31, 2000
Pesticide Type	Repellent
Chemical class	Biochemical
Biopesticide Registration Eligibility Decision (BRED)	May 2000
Cumulative group	N/A
40 C.F.R. Citations	N/A
Non-pesticidal uses	None

Table 2. PMD Use and Usage Information

Summary of Use	Skin applied insect repellent
Use Sites	Human skin
Summary of Usage	No annual usage data has been reported for PMD.
Formulation Types	Aerosol spray, lotion and towelettes
Application Method	Topical
Technical Registrant	S.C. Johnson & Son, Inc (SCJ)
No. of Registrations	4
Restricted Use	No

Registered end-use products (EPs) containing the active ingredient PMD are formulated as sprays, lotions and towelettes to be applied topically on skin or clothing. The first registered product was a spray formulation called UICK II, and now known as OFF! Botanicals Insect Repellent 1 (EPA Reg. No. 4822-509). It was submitted for registration on August 31, 1998, by S.C. Johnson & Son, Inc. A lotion formulation called UICK III, now known as OFF! Botanicals Insect Repellent 2 (EPA Reg 4822-515) was later submitted for registration on May 25, 1999, by S.C. Johnson & Son, Inc. Since then, 4 EPs containing PMD as their active ingredient have been registered for use as topical insect repellents. For a description of the EPA-registered products, including type of formulation, concentration of active ingredient in the product, date of registration, and use sites, see Table 3 below. The registered product

labels for OFF! Botanicals 2, UICK-T and CLAIRE 1 specify that the product is to be applied every 2 hours and not for use on children under the age of 3 years old.

Table 3. Summary of Currently Registered p-Menthane-3,8-diol (PMD)-based Pesticide End-Use Products (EPs)

EPA Registration Number	Product Name (% Active Ingredient, Formulation Type)	Date Registered	Application Rates[1]	Application Methods	Use Sites
4822-509	OFF! (10 %, repellent spray)	March 31, 2000	N/A	Aerosol spray can	Human Skin
4822-515	OFF! BOTANICALS 2 (10 %, repellent lotion)	May 18, 2005	N/A	Lotion	Human Skin
4822-526	UICK-T (8 %, repellent towelettes)	June 03, 2003	N/A	Towelettes	Human Skin
4822-528	CLAIRE 1 (10 %, repellent spray)	September 28, 2004	N/A	Aerosol spray can	Human Skin

[1] Application rates are not applicable to skin applied repellents

D. Anticipated Data Needs and Risk Assessments

Provided below are tables of the current data requirements for biochemical pesticides as set forth in 40 C.F.R. part 158, subpart U. They are arranged by scientific discipline (*i.e.*, product chemistry, human health assessment, non-target organisms, and environmental fate), and descriptions of how the data requirements have been fulfilled. At this time, no data gaps (anticipated data needs) for PMD have been identified. The most recent comprehensive risk assessment for PMD was completed February 26, 1999, in support of the first biochemical registration of PMD, which occurred in May, 2000. Because there are no data gaps for PMD or anticipated data needs, and no additional information has been received on this biochemical since this most recent risk assessment, the Agency does not anticipate the need to conduct a new risk assessment during registration review.

i. Product Chemistry (40 C.F.R. § 158.2030)

Table 4. Summary of Physical and Chemical Characteristics for p-Menthane-3,8-diol (PMD)				
Harmonized Guideline Number	**Data Requirement**	**Has Data Requirement Been Addressed? How?**	**Source**	**MRID No.**
880.1100	Product Identity and Composition	Yes – Study	U.S.EPA 1997	444387-13
880.1200	Description of Staring Materials, Production, and Formulation Process	Yes – Study	U.S.EPA 1997	444387-13
880.1400	Discussion of Formation of Impurities	Yes – Study	U.S.EPA 1997	444387-13
830.1700	Preliminary Analysis	Yes – Study	U.S.EPA 1997	444387-12
830.1750	Certified Limits	Yes – Study	U.S.EPA 1997	444387-13
830.1800	Enforcement Analytical Method	Yes – Study	U.S.EPA 1997	444387-12
830.6302	Color	Yes – Study	U.S. EPA 1997	444387-12
830.6303	Physical State	Yes – Study	U.S. EPA 1997	444387-12
830.6304	Odor	Yes – Study	U.S. EPA 1997	444387-12
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Yes – Study	U.S. EPA 1997	444387-12
830.6315	Flammability	Yes – Study	U.S. EPA 1997	444387-12
830.6319	Miscibility	Yes – Study	U.S. EPA 1997	444387-12
830.7000	pH	Yes – Study	U.S. EPA 1997	444387-12
830.7050	UV/Visible Light Absorption	No[1]		
830.7100	Viscosity	Yes – Study	U.S. EPA 1997	444387-12

Table 4. Summary of Physical and Chemical Characteristics for p-Menthane-3,8-diol (PMD)				
Harmonized Guideline Number	**Data Requirement**	**Has Data Requirement Been Addressed? How?**	**Source**	**MRID No.**
830.7200	Melting Point/Melting Range	Yes - Study	U.S. EPA 1997	444387-12
830.7220	Boiling Point/Boiling Range	Yes – Study	U.S. EPA 1997	444387-12
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	Yes – Study	U.S. EPA 1997	444387-12
830.7520	Particle Size, Fiber Length, and Diameter Distribution	N/A[2]		
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol Water)	Yes – Waiver Request[3]	U.S. EPA 1997	444387-12
830.7840	Water Solubility	Yes – Study	U.S. EPA 1997	444387-12
830.7950	Vapor Pressure	Yes – Study	U.S. EPA 1998	444893-01

[1] The UV/Visible Light Absorption data are only required when Tier II Nontarget Organism and Environmental Fate Data under 40 CFR § 158.2060 are triggered as evidenced by ecological toxic effects demonstrated in Tier I data/information. There are no outdoor uses or direct applications to the environment of PMD. All registered products containing PMD as an active ingredient are applied directly to human skin. Therefore, non-target organism and environmental fate data are not required. Based on this information, the Agency has determined that this data requirement is not applicable.

[2] Particle size, Fiber Length, and Diameter Distribution are not required because PMD has a low vapor pressure (vapor pressure = 1.36×10^{2} mm/Hg) (MRID 444893-01), and unlikely present in the atmosphere. Therefore, the potential for inhalation exposure is not likely to occur.

[3] Partition Coefficent data were waived based on the limited use pattern of the active ingredient (application to human skin).

ii. Human Health Assessment (40 C.F.R. § 158.2050)

Hazard Characterization and Risk

The toxicological database is considered complete for characterizing hazard and assessing risk from PMD. Acute toxicity studies have shown low toxicity for Technical PMD. The oral and dermal LC_{50} (dose required for 50% mortality) are greater than 2000 mg/kg in rats. The inhalation LC_{50} is 2.17 mg/L in rats (MSDS. Santa Cruz Biotechnology, Inc. 2009). PMD is not classified as a skin sensitizer. At high doses (5000 mg/kg) significant dermal irritation was noted at the site of test material application, which included erythema, edema, dermal lesions, necrosis, and desquamation, which dissipated after day 7.

PMD is classified as Toxicity Category I for eye irritation. The diluted end use products are milder, and are placed in Toxicity category II for eye irritation; thus, they must carry the signal word "Warning" on the product label.

In accordance with 40 CFR Part 158.2050, non-food use pattern products are required to be supported by acute inhalation toxicity data on the technical grade active ingredient (TGAI), which results in a respirable material (*e.g.* gas, volatile substance or aerosol particulate), unless it is a straight chain lepidopteran pheromone. The registered products are not pheromones and two of the products are formulated as aerosol sprays. The acute inhalation toxicity study on the TGAI has been waived and instead an acute inhalation toxicity study on the end use product was conducted. The available acute inhalation toxicity study was found to be acceptable (446421-03). The acute inhalation toxicity study on the TGAI was waived due in part to the fact that PMD technical is a solid material at room temperature and the lack of exposure under the registered use conditions. In addition, inhalable material are not expected with PMD technical and with the manufacturing-use product.

Dietary Exposure and Risk Assessment

A dietary (food and drinking water) exposure and risk assessment was not conducted as there are no food uses associated with the PMD pesticide products.

Food tolerances

There are no food uses associated with the PMD pesticide products; therefore, acute and chronic dietary risk assessments were not required, and a numeric tolerance or exemption from the requirement of a tolerance was not needed.

Table 5. Summary of Human Health Assessment Data for p-Menthane-3,8-diol (PMD)

Harmonized Guideline Number	Data Requirement	Has Data Requirement Been Addressed? How?	Source	MRID No. or Other Reference
870.1100	Acute Oral Toxicity - Rat	Yes – Study	U.S. EPA 1997	444387-01
870.1200	Acute Dermal Toxicity	Yes – Study	U.S. EPA 1997	444387-02
870.1300	Acute Inhalation Toxicity	Yes – Waiver Request[1]	U.S. EPA 1999	446421-03
870.2400	Primary Eye Irritation	Yes – Study	U.S. EPA 1997	444387-03
870.2500	Primary Dermal Irritation	Yes – Study	U.S. EPA 1997	444387-04
870.2600	Dermal Sensitization	Yes – Study	U.S. EPA 1997	444387-05

Table 5. Summary of Human Health Assessment Data for p-Menthane-3,8-diol (PMD)				
Harmonized Guideline Number	**Data Requirement**	**Has Data Requirement Been Addressed? How?**	**Source**	**MRID No. or Other Reference**
870.3100	90-Day Oral (one species)	N/A[2]		
870.3250	90-Day Dermal – Rat	Yes – Study	U.S. EPA 1997	444387-10
870.3465	90-Day Inhalation – Rat	N/A[3]		
870.3700	Prenatal Developmental – Rat Preferably	Yes – Study	U.S. EPA 1997	444387-11
870.5100	Bacterial Reverse Mutation Assay	Yes – Study	U.S. EPA 1997	444387-01
870.5300	*In vitro* Mammalian Cell Gene Mutation Assay	Yes – Study	U.S. EPA 1997	444387-06
870.5395	Erythrocyte Micronucleus test	Yes – Study	U.S. EPA 1997	444387-07
870.5375	*In vitro* cytogenetic Chinese Hamster ovary cells. Chromosomal aberration cytogenetics.	Yes – Study	U.S. EPA 1997	444387-08
880.3550	Immunotoxicity Screening in Mice Exposed Dermally	Yes – Study	U.S. EPA 1997	444387-09
870. 6300	Postnatal Developmental Neurotoxicity in rats	Yes-Study	US-EPA 2005	463428-01

[1] The acute inhalation toxicity study on the TGAI was waived due in part that PMD technical is a solid material at room temperature and the lack of exposure under the registered use conditions. In addition, inhalable materials are not expected with PMD technical and with the manufacturing-use product.

[2] The 90-Day Oral study was waived as repeat oral exposure to PMD is not expected based on its use pattern. In addition PMD is not to be applied to food.

[3] The 90-Day Inhalation study was waived because inhalable materials are not expected with PMD technical and with the manufacturing-use product; PMD has a vapor pressure of 1.36×10^{-2} mm/ Hg (MRID 44489301).

iii. Non-target Organisms and Environmental Fate (40 C.F.R. § 158.2060)

There are no outdoor uses or direct applications to the environment. All registered products containing PMD as an active ingredient are applied directly to human skin. Therefore, non-target organism and environmental fate data are not required.

There are no risk concerns for terrestrial non-target organisms and plants based on PMD's labeled use patterns and lack of a complete exposure pathway. Aquatic exposure could be expected via two routes: (1) wash-off from treated skin and clothing when people enter water bodies and (2) wash-off from treated skin and clothing when people bathe or launder clothing. However, based on the biological

breakdown and volatilization of PMD, along with treatment and dilution, the resulting estimated concentrations would be negligible. Therefore EPA has no risk concerns for aquatic organisms. With regard to non-target insects including bees and other pollinators, based on its mode of action EPA expects that terrestrial insects would be repelled from exposures to PMD. As a result, EPA does not expect risks to listed or non-listed non-target organisms.

iv. Product Performance (40 C.F.R. § 158.2070)

Product Performance data on PMD was required to be submitted based upon claims to control public health pests appearing on PMD product labels.

Table 6. Product Performance (Efficacy) Data for p-Menthane-3,8-diol (PMD)-based end use products (EPs)

Data Requirement	Has Data Requirement Been Addressed? How?	Source	MRID No.
830.3700	Yes – Study	U.S. EPA 1998	446421-10
830.3700	Yes – Study	U.S. EPA 1997	450766-01
830.3700	Yes – Study	U.S. EPA 2001	452968-01
830.3700	Yes – Study	U.S. EPA 2001	452968-02
830.3700	Yes – Study	U.S. EPA 2001	452968-03
830.3700	Yes – Study	U.S. EPA 2001	454683-01
830.3700	Yes – Study	U.S. EPA 2001	454881-01
830.3700	Yes – Study	U.S. EPA 2001	454881-02
830.3700	Yes – Study	U.S. EPA 2001	454881-03
830.3700	Yes – Study	U.S. EPA 2001	455642-01
830.3700	Yes – Study	U.S. EPA 2002	456506-09
830.3700	Yes – Study	U.S. EPA 2002	456506-10
830.3700	Yes – Study	U.S. EPA 2003	459304-01
830.3700	Yes – Study	U.S. EPA 2003	459304-02

E. Threatened and Endangered Species

As discussed above, non-target organism and environmental fate data were not required based on PMD's use as an insect repellent. Risk Quotients (RQs) were not calculated as toxicity data were not available. BPPD expects direct and indirect risks to all non-target listed species to be very low given the mode of action of PMD (repellent), the lack of a complete exposure pathway for terrestrial species (applied directly to human skin/clothing and no application to crops, forest, or the environment) and the lack of any reported incidents. Any potential exposure to listed aquatic species resulting from wash-off from treated skin and clothing when people enter water bodies, bathe, or launder clothing would be negligible due to dilution and environmental degradation of residues. Therefore, the EPA anticipates making a "No Effect" determination under the Endangered Species Act (ESA) for direct and indirect effects to listed species and their habitats.

F. Endocrine Disruptor Screening Program

As required by the Administrator under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408(p), the EPA has developed the Endocrine Disruptor Screening Program (EDSP) and has begun to implement the screening program that is to be used to test all pesticides in order to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."

FFDCA section 408(p)(4) authorizes the Administrator, by order, to exempt from the requirements of the Estrogenic Substances Screening Program a biologic substance or other substance if a determination is made that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance.

Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[2] and includes some pesticides scheduled for registration review and chemicals found in water. PMD is not among the group of pesticide active ingredients on the lists to be screened under the EDSP.

The EPA, as part of this Preliminary Work Plan, believes that PMD, the active ingredient involved in this registration review case, likely is a substance that would not produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance. As such, pursuant to Section 408(p)(4), the EPA will determine in the future whether it can exempt PMD from the requirements of the Section 408(p) EDSP. In the event the EPA does determine to exempt this substance from the EDSP, an order will be issued.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website at *http://www.epa.gov/endo/*.

[2] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the second list of chemicals.

G. Incidents

A search of the Office of Pesticide Programs' Incident Data System (IDS) from January 1, 1997, through July 24, 2015, indicated that there are no individual reports of major incidents involving humans associated with the use of PMD in insect repellent products. The reported incidents involved: 1) 211 minor cases involving humans, and 2) 6 minor, 1 moderate and 1 fatality case involving domestic animals. The EPA will consider any incident data or comments submitted in response to this Preliminary Work Plan.

H. Timeline

The projected timeline for registration review of case 6017, p-Menthane-3,8-diol (PMD), is as follows:

Table 7. Registration Review for p-Menthane-3,8-diol (PMD)– Projected Registration Review Timeline

Activities	Estimated Month/Year
Opening the Docket	
Open Docket and 60-Day Public Comment Period for PMD	December 2015
Close Public Comment Period	February 2016
Issue Final Work Plan	June 2016
Issue Data Call-in	N/A
Data Submission	N/A
Open 30-Day Public Comment Period for Draft Risk Assessments	N/A
Close Public Comment Period	N/A
Open 60-Day Public Comment Period for Proposed Registration Review Decision	December 2016
Close Public Comment Period	February 2017
Final Decision	June 2017
***Estimated Total (years)**	**1 year and 6 months**

* This schedule is subject to revision should unforeseen issues arise during the registration review process. In the event an issue arises, such as the failure to acquire an EDSP exemption, an amended Final Work Plan will be issued at that time. That Final Work Plan will identify any newly anticipated data needs and set forth a new timeline.

I. Guidance for Commenters

The public is invited to comment on the EPA's Preliminary Work Plan and rationale. The areas below highlight topics of special interest to the EPA where comments, data submissions, or reference to sources of additional information could be of particular use. The EPA will consider all comments, as well as any

additional information or data provided in a timely manner, prior to issuing a Final Work Plan for this case.

i. Environmental Justice

The EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to PMD, compared to the general population. **Please comment if you are aware of any subpopulations that may have atypical, unusually high exposure compared to the general population.**

ii. Water Quality

PMD is not identified as a cause of impairment for any water bodies listed as impaired under Section 303(d) of the Clean Water Act.[3] In addition, no Total Maximum Daily Loads (TMDLs) have been developed for PMD. More information on impaired water bodies and TMDLs can be found at the EPA's website.[4] **The EPA invites submission of water quality data for these pesticides.** To the extent possible, data should conform to the quality standards in Appendix A of the *Office of Pesticide Program's (OPP) Guidance for Submission of State and Tribal Water Quality Monitoring Data, March 2014: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process*[3] to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

iii. Trade Irritants

Through the registration review process, the EPA intends to solicit information on trade irritants, and to the extent feasible, take steps toward facilitating irritant resolution. The EPA will work to harmonize tolerance and international Maximum Residue Limits (MRLs) and may modify tolerance levels to do so, when possible. **Growers and other stakeholders are asked to comment** on any trade irritant issues resulting from lack of MRLs or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

There are no food uses associated with the registration of PMD as an active ingredient in topical repellents; thus no tolerance or exemption from the requirement of a tolerance has been established, and there are no known MRLs for PMD. Therefore, the EPA does not anticipate that current uses of PMD will pose concerns as trade irritants.

---

[3] This is based on information provided at http://www.epa.gov/owow/tmdl/.

[4] *This document can be found at* http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm

iv. Additional Information

Stakeholders are also specifically asked to provide information and data that will assist the EPA in refining the risk assessments. The EPA is interested in obtaining the following regarding PMD:

- Confirmation on the following label information:
  - *Sites of application*
  - *Formulations*
  - *Application methods and equipment*
  - *Maximum application rates*
  - *Frequency of application, application intervals, and maximum number of applications*
  - *Geographic limitations on use*
- Use or potential use distribution (e.g., geographical distribution of relevant use sites)
- Application timing
- Typical application interval
- State or local use restrictions
- Foreign technical registrants not listed above who supply technical PMD to the US market

J. Next Steps

After the 60-day comment period closes, the EPA will review and respond to any comments received in a timely manner and then issue a final work plan for PMD case #6017.

II. FACT SUMMARY FOR CASE #6017

Table 8. Background Information for the p-Menthane-3,8-diol (PMD) Registration Review

First Registered	Currently Registered Pesticide Products[1]	Publicly Available EPA Science and Regulatory Documents[2]	Additional Risk Assessment Needed? (Yes or No)		
			Product Chemistry	Human Health Assessment	Nontarget Organisms and Environmental Fate
2000	1 manufacturing-use product and 4 end-use products	BPPD Fact Sheet Technical Document (BRED)	No	No	N/A[3]

[1] See Table 3 for additional information on the currently registered products. The labels for these products can be found in the Pesticide Product Label System.

[2] Regulatory documents can be found at: http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:0::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:1968

[3] Non-target organisms and environmental fate data were not required since all registered products containing PMD are only applied directly to human skin, with no exposure to non-target species or the environment.

III. BIBLIOGRAPHY

A. Studies Submitted in Support of Registration of PMD and derived end-use products: See section IV. Appendix.

B. U.S. Environmental Protection Agency Data Reviews and Risk Assessment

The following table lists the titles and study report dates reviewed in BPPD for registration of p-Menthane-3,8-diol (PMD Technical) EPA Registration 4822-499, and derived end-use products. Product Chemistry; Acute and Chronic Human Health Toxicity; and Efficacy Studies.

Table 9. Data Reviews and Risk Assessments for p-Menthane-3,8-diol (PMD) and derived end-use products.

Study Report Date	Title	Reviewer from BPPD	MRID
5/15/2003	Response to SC Johnson Email dated April 22, 2003, regarding UICK-T (EPA Reg. No. 4822-526, containing 8 % PMD.	Mary Clock-Rust	456152-01 to 456152-05
03/12/2003	Science review of Efficacy studies in support of registration of OFF! Botanicals 2 (EPA Reg. No. 4822-515), containing 10% PMD	Nina Simeonova	454683-01 to 454683-03
02/26/1999	Risk Assessment and mammalian Toxicology reviews of PMD Technical, Granola 97 (EPA Reg. No. 4822-499), containing 99 % PMD (65 % cis and 34% trans isomers)	Sheryl Reilly	444387-01 to 444387-13; 444893-01 & 444878-01
09/06/2000	Review of product performance of OFF! Botanicals 2 (EPA Reg. No. 4822-515), containing 10% PMD.	Robyn Rose	450766-01
05/20/2004	Review of amended product performance of OFF! Botanicals 2 (former UICK 3) (EPA Reg. No. 4822-515), containing 10% PMD.	Russell Jones	459304-01 to 459304-01
09/19/2002	Review of product performance of UICK II (EPA Reg. No. 4822-509), containing 10% PMD.	Russell Jones	455642-01
02/24/2000	Review of product chemistry and Acute toxicity of UICK 3 (EPA Reg. No. 4822-515), containing 10% PMD.	Russell Jones	448367-01 to 448367-07
09/27/1999	Secondary review of DERs on Acute Toxicity studies with UICK II (EPA Reg. No. 4822-509), containing 10% PMD.	Roger Gardner	446421-01 to 446421-07
07/21/1998	Review of product chemistry for registration of PMD Technical, Granola 97 (EPA Reg. No. 4822-499), containing 99 % PMD (65 % cis and 34% trans isomers).	Freshteh Toghrol	444387- 12 to 444387-13 & 444893-01
01/20/2004	Science review in support of registration of Claire-1 (EPA Reg. No. 4822-528, containing 10% PMD.	Manying Xue	456506-01 to 456506-10
04/18/2002	Secondary review of Oil of Lemon Eucalyptus and revision to Human Health Risk Assessment	Roger Gardner	455401-01 to 455401-03
02/04/1999	Registration of MUP Citrodiol (EPA Reg. No. 305-59, 100% Oil of Eucalyptus, containing 65% PMD	Carol Frazer	446242-01 to 446242-10; 446240-01 to 446240-03; 446239-01 to 446239-03; 446241-01 to 446241-05

02/04/2005	PMD Postnatal developmental neurotoxicity study in rats.	Roger Gardner	463428-01
04/30/2003	Review of product chemistry and Eye Irritation studies for registration of UICK-T (EPA Reg. No. 4822-526, containing 8 % PMD.	Mary Clock- Rust	456152-01 to 456152-05
06/09/2000	Secondary review of DERs on Oil of Lemon Eucalyptus Technical.	Roger Gardner	450452-01 to 450452-03; 450567-01

IV. APPENDIX

Studies Submitted in Support of Registration of PMD and derived End-Use products (EPs).

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
44186100	Primavera Labs. Inc. (1996) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Eucalyptus Citriodora Crystal and Bioveramar III. Transmittal of 7 Studies.	30-Nov-1996
44186101	Smith, T.; Johnston, J. (1996) Eucalyptus Citriodora Crystal--Product Chemistry--First of a Series: Lab Project Number: 22242-96. Unpublished study prepared by Shaw Mudge & Co. and RSA Corp. 14 p.	30-Nov-1996
44186102	Tong, C. (1996) Acute Oral Toxicity Study in Rats on TREO Lotion with Chinese Crystal: Lab Project Number: 202081-04: PCL TOX/ORALLD50.007. Unpublished study prepared by SGS U.S. Testing Co. Inc. 18 p.	30-Nov-1996
44186103	Tong, C. (1996) Acute Dermal Toxicity Study in Rabbits on TREO Lotion with Chinese Crystal: Lab Project Number: 202081-01: PCL TOX DERML50.008. Unpublished study prepared by SGS U.S. Testing Co. Inc. 18 p.	30-Nov-1996
44186104	Tong, C. (1996) Eucalyptus Citriodora Crystal--Acute Inhalation Toxicity Testing Status Update (in Rats): Lab Project Number: PCL TOX/INHAL50.009: TESTPLAN/T202880: TRPT\202880.IT1. Unpublished study prepared by SGS U.S. Testing Co. Inc. 4 p.	30-Nov-1996
44186105	Tong, C. (1996) Eye Irritation Study in Rabbits on TREO Lotion with Chinese Crystal: Lab Project Number: 202081-03: PCL TOX EYEIREPA.011. Unpublished study prepared by SGS U.S. Testing Co. Inc. 19 p.	30-Nov-1996
44186106	Tong, C. (1996) Skin Irritation Study in Rabbits on TREO Lotion with Chinese Crystal: Lab Project Number: 202081-02: PCL TOX DERMIRRI.010. Unpublished study prepared by SGS U.S. Testing Co. Inc. 17 p.	30-Nov-1996
44186107	Tong, C. (1996) Skin Sensitization (Kligman) Study in Guinea Pigs on TREO Lotion with Chinese Crystal: Lab Project Number: 202081-05: PCL TOX GPSKINMT.016. Unpublished study prepared by SGS U.S. Testing Co. Inc. 24 p.	30-Nov-1996

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
44186200	Primavera Laboratories, Inc. (1996) Submission of Product Chemistry Data in Support of the Application for Registration of Bioveramar III. Transmittal of 1 Study.	30-Nov-1996
44186201	Smith, T. (1996) Bioveramar III--Product Chemistry--First of a Series: (Product Identity and Composition): Lab Project Number: 22243-96. Unpublished study prepared by Shaw Mudge & Co. 9 p.	30-Nov-1996
44210300	Primavera Laboratories, Inc. (1996) Submission of Product Chemistry Data in Support of the Registration for Bioveramar III. Transmittal of 1 Study.	30-Nov-1996
44210301	Smith, T. (1996) Bioveramar III--Product Chemistry--Third of a Series (Physical and Chemical Characteristics): Lab Project Number: 22243-96. Unpublished study prepared by Shaw Mudge & Co. 4 p.	30-Nov-1996
44210500	Primavera Labs., Inc. (1996) Submission of Product Chemistry Data in Support of the Application for Registration of the Eucalyptus Citriodora Crystal Containing Product Bioveramar III. Transmittal of 1 Study.	30-Nov-1996
44210501	Smith, T. (1996) Bioveramar III--Product Chemistry--Third of a Series (Physical and Chemical Characteristics): Lab Project Number: 22243-96: H:\DMS\HGBAILEY\0013846.01. Unpublished study prepared by Shaw Mudge and Co. 4 p.	30-Nov-1996
44284800	Primavera Labs. (1997) Submission of Toxicity Data in Support of the Application for Registration of Eucalyptus Citriodora Crystal. Transmittal of 1 Study.	30-Nov-1996
44284801	Grilli, A. (1996) Ames Salmonella Microsome Mutagenesis Assay on TREO Lotion with 2% Chinese Crystal: Lab Project Number: 202130: 202130R: M202130. Unpublished study prepared by SGS U.S. Testing Co., Inc. 18 p.	30-Nov-1996
44285500	Primavera Labs., Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of Primavera Botanical Insect Repellent Lotion, SPFs 15 & 30. Transmittal of 3 Studies.	08-May-1997
44285501	Young, R. (1997) Primavera Botanical Insect Repellent Lotion, SPFs 15 & 30: Product Chemistry--First of a Series: Lab Project Number: KY97-1A. Unpublished study prepared by KY Labs. 46 p.	08-May-1997
44285502	Young, R. (1997) Primavera Botanical Insect Repellent Lotion--Product Chemistry--Second of a Series: Lab Project Number: KY97-1B. Unpublished study prepared by KY Labs. 7 p.	08-May-1997
44285503	Iatropoulos, M. (1997) Primavera Botanical Insect Repellent Lotion SPFs 15 & 30: Product Chemistry--Third of a Series: Lab Project Number: MJI97-10. Unpublished study prepared by Labpath Management, Inc. 4 p.	08-May-1997
44324600	Primavera Labs, Inc. (1997) Submission of Toxicity Data in Support of the Application for Registration of Eucalyptus Citriodora Crystal. Transmittal of 1 Study.	15-Jul-1997
44324601	Tong, C.; Breheny, J. (1997) Acute Inhalation Toxicity Limit Test, 4 Hours on Bioveramar (M-2195) Solution Containing 32% Eucrys (Eucalyptus Citriodora Crystal) (in Rats): Lab Project	15-Jul-1997

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
	Number: 202880: 202880.AM1: PCL TOX/INHALC50.009. Unpublished study prepared by SGS U.S. Testing Co., Inc. 24 p.	
44438700	S.C. Johnson & Son, Inc. (1997) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Granola 97. Transmittal of 13 Studies.	28-Nov-1997
44438701	Bonnette, K. (1997) **An Acute Oral Toxicity Study of Granola 97 in Rats**: Final Report: Lab Project Number: 3068.64: S97.005.3068: 346. Unpublished study prepared by Springborn Labs., Inc. 54 p.	28-Nov-1997
44438702	Bonnette, K. (1997) **An Acute Dermal Toxicity Study of Granola 97 in Rabbits**: Final Report: Lab Project Number: 3068.65: S97.005.3068: 346. Unpublished study prepared by Springborn Labs., Inc. 35 p.	28-Nov-1997
44438703	Bonnette, K. (1997) **A Primary Eye Irritation Study of Granola 97 in Rabbits**: Final Report: Lab Project Number: 3068.66: S97.005.3068: 346. Unpublished study prepared by Springborn Labs., Inc. 29 p.	28-Nov-1997
44438704	Bonnette, K. (1997) **A Primary Skin Irritation Study of Granola 97 in Rabbits**: Final Report: Lab Project Number: 3068.67: 346: S97.005.3068. Unpublished study prepared by Springborn Labs., Inc. 27 p.	28-Nov-1997
44438705	Bonnette, K. (1997) **A Dermal Sensitization Study of Granola 97 in Guinea Pigs**: Modified Buehler Design: Final Report: Lab Project Number: 3068.68: 346: S97.005.3068. Unpublished study prepared by Springborn Labs., Inc. 47 p.	28-Nov-1997
44438706	San, R.; Clarke, J. (1997) **In vitro Mammalian Cell Gene Mutation Test with Granola 97**: (SCJ NB # 14735R108): Amended Final Report II: Lab Project Number: G97BF49.702: GRANOLA 97 (GLP # 346; SCJ NB # 14735R108). Unpublished study prepared by MA BioServices, Inc. 37 p.	28-Nov-1997
44438707	Gudi, R.; Ritter, P. (1997) **Mammalian Erythrocyte Micronucleus Test with Granola 97** (SCJ NB # 14735R108): Amended Final Report II: Lab Project Number: G97BF49.123001: GRANOLA 97 (GLP #346; SCJ NB # 14735R108). Unpublished study prepared by MA BioServices, Inc. 47 p.	28-Nov-1997
44438708	Gudi, R.; Schadly, E. (1997) **In vitro Mammalian Cytogenetic Test Using Chinese Hamster Ovary (CHO) Cells with Granola 97** (SCJ NB # 14735R108): Amended Final Report II: Lab Project Number: G97BF49.335: GRANOLA 97 (GLP # 346; SCJ NB # 14735R108). Unpublished study prepared by MA BioServices, Inc. 51 p.	28-Nov-1997
44438709	House, R.; Johnson, W.; Krueger, J. (1997) **Immunotoxicity Screening Study in Mice Exposed Dermally to Granola 97:** Final Report: Lab Project Number: L08686. Unpublished study prepared by IIT Research Institute. 43 p. {OPPTS 880.3550}	28-Nov-1997
44438710	Rush, R. (1997) **A 90-Day Dermal Toxicity Study of Granola 97 in Rats**: Final Report: Lab Project Number: 3068.63: 346: 129027. Unpublished study prepared by Springborn Labs., Inc. 403 p.	28-Nov-1997

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
44438711	Wakefield, A. (1997) **Rat Prenatal Developmental Toxicity Study with Granola 97**: (SCJ NB# 14735R108): Final Report: Lab Project Number: 6106-116. Unpublished study prepared by Covance Labs., Inc. 199 p. {OPPTS 870.3700}	28-Nov-1997
44438712	Welch, K. (1997) **Physical and Chemical Characteristics of Granola 97**: Lab Project Number: 346A1: 14735R108-A1: ARSP-PC-129026. Unpublished study prepared by S.C. Johnson & Son, Inc. 71 p. {OPPTS 830.1700, 830.1800, 830.830.6302, 830.6303, 830.6304, 830.7200, 830.7300, 830.7840, 830.6313, 830.6315, 830.7100}	28-Nov-1997
44438713	Uick, H. (1997) **Product Chemistry Data for Granola 97** Formula Number 14735R108: Lab Project Number: 346. Unpublished study prepared by S.C. Johnson and Son, Inc. 34 p. {OPPTS 880.1100, 880.1200, 880.1400, 880.1750}	28-Nov-1997
44487800	S.C. Johnson & Son, Inc. (1997) Submission of Toxicity Data in Support of the Application for Registration of Granola 97. Transmittal of 1 Study.	28-Nov-1997
44487801	Wagner, V.; Walton, E. (1997) **Bacterial Reverse Mutation Assay with Granola 97** (SCJ NB # 14735R108): Amended Final Report II: Lab Project Number: GRANOLA 97: G97BF49.502: SPGT502. Unpublished study prepared by MA BioServices, Inc. 47 p.	28-Nov-1997
44489300	S.C. Johnson & Son, Inc. (1998) Submission of Product Chemistry Data in Support of the Application for Registration of Granola 97. Transmittal of 1 Study.	11-Feb-1998
44489301	Morrissey, M. (1998) **Vapor Pressure Determination of Granola 97**: Final Report: Lab Project Number: COVANCE 6106-118. Unpublished study prepared by Covance Laboratories, Inc. 47 p. {OPPTS 830.7950}	11-Feb-1998
44623900	Wisconsin Pharmacal Co. (1998) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Repel Natural Insect Repellent Non-Aerosol Pump. Transmittal of 3 Studies.	07-Aug-1998
44623901	Cudnohoske, E. (1998) Product Chemistry Data of Repel Natural Pump: Lab Project Number: 0625982. Unpublished study prepared by Wisconsin Pharmacal Co., Inc. 23 p. {OPPTS 830.1800}	07-Aug-1998
44623902	Kukulinski, M. (1998) Primary Eye Irritation Study (in Rabbits): Repel Natural Pump: Final Report: Lab Project Number: 98-0201-1. Unpublished study prepared by Tox Monitor Labs., Inc. 17 p.	07-Aug-1998
44623903	Kukulinski, M. (1998) Primary Dermal Irritation Study (in Rabbits): Repel Natural Pump: Final Report: Lab Project Number: 98-0201-2. Unpublished study prepared by Tox Monitor Labs., Inc. 9 p.	07-Aug-1998
44624000	Wisconsin Pharmacal Company (1998) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Repel Natural Insect Repellent Lotion. Transmittal of 3 Studies.	07-Aug-1998
44624001	Cudnohoske, E. (1998) Product Chemistry Data of Repel Natural Lotion: Lab Project Number: 0625984. Unpublished study prepared by Wisconsin Pharmacal Company, Inc. 23 p. {OPPTS 830.1800}	07-Aug-1998

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
44624002	Kukulinski, M. (1998) Primary Eye Irritation Study (in Rabbits): Final Report: Repel Natural Lotion: Lab Project Number: 98-0203-1. Unpublished study prepared by Tox Monitor Laboratories, Inc. 17 p.	07-Aug-1998
44624003	Kukulinski, M. (1998) Primary Dermal Irritation Study (in Rabbits): Final Report: Repel Natural Lotion: Lab Project Number: 98-0203-2. Unpublished study prepared by Tox Monitor Laboratories, Inc. 9 p.	07-Aug-1998
44624100	Wisconsin Pharmacal Co., Inc. (1998) Submission of Toxicity, Efficacy, and Product Chemistry Data in Support of the Application for Registration of Repel Natural Insect Repellent Aerosol. Transmittal of 5 Studies.	07-Aug-1998
44624101	Cudnohoske, E. (1998) Product Chemistry Data of Repel Natural Aerosol: Lab Project Number: 0625983. Unpublished study prepared by Wisconsin Pharmacal Company, Inc. 25 p. {OPPTS 830.1800}	07-Aug-1998
44624102	Kukulinski, M. (1998) Primary Eye Irritation Study (in Rabbits): Repel Natural Aerosol: Final Report: Lab Project Number: 98-0202-1. Unpublished study prepared by Tox Monitor Laboratories, Inc. 17 p.	07-Aug-1998
44624103	Kukulinski, M. (1998) Primary Dermal Irritation Study (in Rabbits): Repel Natural Aerosol: Final Report: Lab Project Number: 98-0202-2. Unpublished study prepared by Tox Monitor Laboratories, Inc. 9 p.	07-Aug-1998
44624104	Kukulinski, M. (1998) Acute Inhalation Toxicity Study (in Rats): Repel Natural Aerosol: Final Report: Lab Project Number: 98-0193-3. Unpublished study prepared by Tox Monitor Laboratories, Inc. 16 p.	07-Aug-1998
44624105	Dillon, R.; Curtis, C.; Trigg, J. et al. (1998) Efficacy Studies: Repel Natural Aerosol: Lab Project Number: 080598. Unpublished study prepared by Medical Advisory Services for Travelers Abroad, Ltd., and London School of Hygiene and Tropical Medicine. 119 p.	07-Aug-1998
44642100	S.C. Johnson & Son, Inc. (1998) Submission of Product Chemistry, Efficacy, Toxicity, Exposure and Risk Assessment Data in Support of the Application for Registration of UICK II. Transmittal of 11 Studies.	31-Aug-1998
44642101	Bonnette, K. (1998) An Acute Oral Toxicity Study in Rats with Moeller Plus: Amended Final Report: Lab Project Number: 359: 3068.105. Unpublished study prepared by Springborn Labs., Inc. 25 p.	31-Aug-1998
44642102	Bonnette, K. (1998) An Acute Dermal Toxicity Study in Rabbits with Moeller Plus: Amended Final Report: Lab Project Number: 359: 3068.106. Unpublished study prepared by Springborn Labs., Inc. 31 p.	31-Aug-1998
44642103	Bonnette, K. (1998) An Acute Nose-Only Inhalation Toxicity Study in Rats with UICK-2: Final Report: Lab Project Number: 377: 3068.154. Unpublished study prepared by Springborn Labs., Inc. 50 p.	31-Aug-1998

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
44642104	Bonnette, K. (1998) A Primary Eye Irritation Study in Rabbits with UICK-2: Amended Final Report: Lab Project Number: 377: 3068.153. Unpublished study prepared by Springborn Labs., Inc. 37 p.	31-Aug-1998
44642105	Bonnette, K. (1998) A Primary Skin Irritation Study in Rabbits with Moeller Plus: Amended Final Report: Lab Project Number: 359: 3068.109. Unpublished study prepared by Springborn Labs., Inc. 29 p.	31-Aug-1998
44642106	Bonnette, K. (1998) A Dermal Sensitization Study in Guinea Pigs with Moeller Plus: Modified Buehler Design: Amended Final Report: Lab Project Number: 359: 3068.110. Unpublished study prepared by Springborn Labs., Inc. 49 p.	31-Aug-1998
44642107	Vendetti, N. (1998) Repeated Insult Patch Study with UICK-2 (Human Volunteers): Lab Project Number: 981020: TKL-1000M. Unpublished study prepared by TKL Research, Inc. 46 p.	31-Aug-1998
44642108	Welch, K. (1998) Physical and Chemical Characteristics for UICK-2: Lab Project Number: 377A1: 1504R59-2A1: ARSP-PC-133211. Unpublished study prepared by S.C. Johnson & Son, Inc. 11 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.7300, 830.6315, 830.7100}	31-Aug-1998
44642109	Hildebrandt, D. (1998) Product Chemistry Data for UICK II: Lab Project Number: 00A169. Unpublished study prepared by S.C. Johnson & Son, Inc. 25 p. {OPPTS 830.1750, 830.1600, 830.1650, 830.1620, 830.1800, 830.1670}	31-Aug-1998
44642110	Verwey, R. (1998) Determining Repellency of Uick 2 (10% p-menthane 3,8 diol) Against Biting Gnats (Commonly called no-see-ums)(Culicoides spp.), Biting Flies (Black Flies)(Simulium spp.) and Mosquitoes (Culicidae) in the Field: Amended Final Report: Lab Project Number: 377E1: ENT-REP-002: GLP 377E1. Unpublished study prepared by S.C. Johnson & Son, Inc. 24 p.	31-Aug-1998
44642111	Driver, J.; Ginevan, M.; Pandian, M. (1998) Hazard Identification and Evaluation of Potential Exposures and Health Risks Associated with Consumer Use of p-menthane 3,8 diol in UICK II Insect Repellent: Lab Project Number: UICK II 01-98. Unpublished study prepared by risksciences.com, L.L.C. 28 p.	31-Aug-1998
44692500	Wisconsin Pharmacal Company (1998) Submission of Product Chemistry Data in Support of the Application for Registration of Extract of Lemon Eucalyptus. Transmittal of 1 Study.	13-Nov-1998
44692501	Brookman, D.; Curry, K. (1998) Supplemental Product Chemistry Information for Extract of Lemon Eucalyptus: Lab Project Number: WPC-111198. Unpublished study prepared by Wisconsin Pharmacal Company. 27 p.	13-Nov-1998
44784700	Wisconsin Pharmacal Company (1999) Submission of Toxicity Data in Support of the Application for Registration of Oil of Lemon Eucalyptus. Transmittal of 1 Study.	11-Mar-1999
44784701	Stewart, R.; Burin, G. (1999) Oil of Lemon Eucalyptus Technical: Summary of Comparative Toxicity: Lab Project Number: WPC-9903. Unpublished study prepared by Wisconsin Pharmacal Company. 46 p.	11-Mar-1999
44833400	Wisconsin Pharmacal Company (1999) Submission of Toxicity Data in Support of the Application for Registration of Citriodiol. Transmittal of 1 Study.	20-May-1999

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
44833401	Stewart, R.; Burin, G.; Brookman, D. (1999) Oil of Lemon Eucalyptus Technical: Basis for an Assessment of Risk: Lab Project Number: WPC-9904A. Unpublished study prepared by Wisconsin Pharmacal Company. 388 p.	20-May-1999
44836700	S.C. Johnson and Son, Inc. (1999) Submission of Product Chemistry, Toxicity, Risk Assessment and Exposure Data in Support of the Application for Registration of UICK 3. Transmittal of 8 Studies.	25-May-1999
44836701	Bonnette, K. (1999) An Acute Oral Toxicity Study in Rats with UICK-3: Final Report: Lab Project Number: 390: 3068.187: 15028R21. Unpublished study prepared by Springborn Laboratories, Inc. 23 p.	25-May-1999
44836702	Bonnette, K. (1999) An Acute Dermal Toxicity Study in Rabbits with UICK-3: Amended Final Report: Lab Project Number: 3068.188: 15028R21: 390. Unpublished study prepared by Springborn Laboratories, Inc. 34 p. {OPPTS 870.1200}	25-May-1999
44836703	Bonnette, K. (1999) A Primary Eye Irritation Study in Rabbits with UICK-3: Final Report: Lab Project Number: 390: 15028R21: 3068.190. Unpublished study prepared by Springborn Laboratories, Inc. 29 p. {OPPTS 870.2400}	25-May-1999
44836704	Bonnette, K. (1999) A Primary Skin Irritation Study in Rabbits with UICK-3: Final Report: Lab Project Number: 390: 3068.189: 15028R21. Unpublished study prepared by Springborn Laboratories, Inc. 29 p. {OPPTS 870.2500}	25-May-1999
44836705	Vendetti, N. (1999) Repeated Insult Patch Study with UICK-3: (in Humans): Lab Project Number: 981052: 24051: 15028R21. Unpublished study prepared by TKL Research, Inc. 48 p.	25-May-1999
44836706	Lu, A. (1999) Product Chemistry Data for UICK 3: Lab Project Number: 00A167. Unpublished study prepared by S.C. Johnson and Son, Inc. 66 p. {OPPTS 830.1550, 830.1620, 830.1750, 830.1800}	25-May-1999
44836707	Smith, G. (1999) Physical and Chemical Characteristics of UICK 3: Lab Project Number: 15028R21: 390A2: 15028R21-A2. Unpublished study prepared by S.C. Johnson and Son, Inc. 21 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6315}	25-May-1999
44836708	Driver, J.; Ginevan, M.; Pandian, M. (1998) Hazard Identification and Evaluation of Potential Exposures and Health Risks Associated with Consumer use of p-Menthane-3,8-diol in UICK 3 Insect Repellent--Lotion Formulation: Lab Project Number: RS.C 01-006-98. Unpublished study prepared by risksciences.com, LLC. 28 p.	25-May-1999
45029100	Wisconsin Pharmacal Company (2000) Submission of Efficacy Data in Support of the Application for Registration of Insect Repellents Containing Oil of Lemon Eucalyptus in Oil, Aerosol, and Pump Spray. Transmittal of 1 Study.	01-Feb-2000
45029101	Wundrock, M. (2000) Laboratory Testing for Insect Repellents Efficacy-Oil of Lemon Eucalyptus: Lab Project Number: WP 99 8-8. Unpublished study prepared by USDA. 17 p.	01-Feb-2000

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
45045200	WPC Brands, Inc. (2000) Submission of Toxicity Data in Support of the Application for Registration of Citridiol, Repel Natural Insect Repellent Non-Aerosol Pump, Repel Natural Insect Repellent Aerosol and Repel Natural Insect Repellent Lotion. Transmittal of 3 Studies.	18-Feb-2000
45045201	Cifone, M. (2000) L5178Y TK +/-Mouse Lymphoma Forward Mutation Assay with a Confirmation Assay with Oil of Lemon Eucalyptus: Final Report: Lab Project Number: 20901-0-431 OECD. Unpublished study prepared by Covance Labs., Inc. 34 p.	18-Feb-2000
45045202	Myhr, B. (2000) In vivo Mouse Micronucleus Assay with Oil of Lemon Eucalyptus: Final Report: Lab Project Number: 20901-0-455OECD. Unpublished study prepared by Covance Labs., Inc. 27 p.	18-Feb-2000
45045203	Parker, R. (2000) 28-Day Dermal Toxicity Study of Oil of Lemon Eucalyptus in Rats: Final Report: Lab Project Number: 720-004. Unpublished study prepared by Argus Research Labs., Inc. 310 p. {OPPTS 870.3200}	18-Feb-2000
45056700	WPC Brands (2000) Submission of Toxicity Data in Support of the Application for Registration of Citriodiol, Repel Natural Insect Repellent Lotion, Repel Natural Insect Repellent Non-Aerosol Pump, and Repel Natural Insect Repellent Aerosol. Transmittal of 1 Study.	18-Feb-2000
45056701	Parker, R. (2000) Dermal Developmental Toxicity Study of Oil Of Lemon Eucalyptus in Rats: Final Report: Lab Project Number: 720-005. Unpublished study prepared by Argus Research Laboratories, Inc. 158 p. {OPPTS 870.3700}	18-Feb-2000
45061500	WPC Brands, Inc. (2000) Submission of Efficacy Data in Support of the Application for Registration of Citriodiol, Repel Natural Insect Repellent Lotion, Repel Natural Insect Repellent Non-Aerosol Pump, and Repel Natural Insect Repellent Aerosol. Transmittal of 2 Studies.	01-Feb-2000
45061501	Carroll, S. (1999) Laboratory Test-Deer Tick Repellent Efficacy/Duration (Using Nymphal Ixodes pacificus, the Western Black-legged Tick) of Wisconsin Pharmacal Company Formulae: 1) Natural Insect Repellent Lotion (PF #7030B, Lot #092999) 2) Natural Insect Repellent Pump (Spray) (ID #0625982, Lot #0927991): Lab Project Number: WP 99 10 16. Unpublished study prepared by Carroll-Loye Biological Research. 16 p.	01-Feb-2000
45061502	Carroll, S. (1999) Field Test-Mosquito Repellent Efficacy/Duration of Wisconsin Pharmacal Company Formulae: 1) Natural Insect Repellent Lotion (PF #7030B, Lot #092999) 2) Natural Insect Repellent Pump (Spray) (ID #0625982, Lot #0927991): Lab Project Number: WP 99 10 03. Unpublished study prepared by Carroll-Loye Biological Research. 27 p.	01-Feb-2000
45076600	S.C. Johnson and Son, Inc. (2000) Submission of Efficacy Data in Support of the Application for Registration of UICK 3. Transmittal of 1 Study.	29-Mar-2000
45076601	Verwey, R. (1999) Determining Repellency of Uick-3 (10% p-menthane 3,8 diol) Against Biting Gnats (Commonly Called No-See-Ums)(Culicoides spp), Biting Flies (Black Flies) (Simulium spp.) and Mosquitoes (Culicidae) in the Field: Interim Report: Lab Project Number: 390E2. Unpublished study prepared by S.C. Johnson and Son, Inc. 24 p.	29-Mar-2000

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
45296800	S.C. Johnson and Son, Inc. (2000) Submission of Efficacy Data in Support of the Registration of OFF! Botanicals 2. Transmittal of 3 Studies.	02-Jan-2001
45296801	Verwey, R. (2000) Determining Repellency of Uick-3 (10% p-menthane 3,8 diol) Against Biting Gnats (Commonly Called No-See-Ums) (Culicoides spp.), Biting Flies (Black Flies) (Simulium spp.) and Mosquitoes (Culicidae) in the Field: Lab Project Number: 135060: 390E2. Unpublished study prepared by S.C. Johnson & Son, Inc. 24 p.	02-Jan-2001
45296802	Verwey, R. (2000) Determining Repellency of Uick-3 (10% p-menthane 3,8 diol) Against Ticks (Ixodes scapularis Adults and Amblyomma americanum Adults): Lab Project Number: 135060: 390E3. Unpublished study prepared by S.C. Johnson & Son, Inc. 20 p.	02-Jan-2001
45296803	Verwey, R. (2000) Determining Repellency of Uick-3 Against Chiggers in the Laboratory: Lab Project Number: 135058: 390E1. Unpublished study prepared by S.C. Johnson & Son, Inc. 20 p.	02-Jan-2001
45468300	S.C. Johnson & Son, Inc. (2001) Submission of Efficacy Data in Support of the Registration of OFF Botanicals 2 and p-Menthane-3,8-diol Technical. Transmittal of 1 Study.	01-Aug-2001
45468301	Ropiak, D. (2001) Determining Repellency of Uick-3 (10% p-menthane 3,8 diol) Against Biting Gnats (Commonly Called No-See-Ums) (Culicoides spp.), Biting Flies (Black Flies) (Simulium spp.) and Mosquitoes (Culicidae) in the Field: Amended Interim Report #3: Lab Project Number: 390: 135060: 390E2. Unpublished study prepared by S.C. Johnson and Son, Inc. 31 p.	01-Aug-2001
45488100	S.C. Johnson & Son, Inc. (2001) Submission of Efficacy Data in Support of the Amended Registration of Off! Botanicals 2. Transmittal of 3 Studies.	30-Aug-2001
45488101	Verwey, R. (2000) Determining Repellency of Uick-3 (10% p-methane 3,8 diol) Against Biting Gnats (commonly called no see-ums)(Culicoides spp), Biting Flies (Black Flies)(Simulium spp.) and Mosquitoes (Culicidae) in the Field: Interim Report #2: Lab Project Number: 390E2. Unpublished study prepared by S.C. Johnson and Son, Inc. 31 p.	30-Aug-2001
45488102	Ropiak, D. (2001) Determining Repellency of Uick-3 (10% p-menthane 3,8 diol) Against Ticks (Ixodes scapularis and Amblyomma americanum Adults) in the Laboratory: Lab Project Number: 390E3. Unpublished study prepared by S.C. Johnson and Son, Inc. 25 p.	30-Aug-2001
45488103	Verwey, R. (2001) Determining Repellency of Uick-3 Against Chiggers in the Laboratory: Amended Final Report: Lab Project Number: 390E1. Unpublished study prepared by S.C. Johnson and Son, Inc. 22 p.	30-Aug-2001
45564200	S.C. Johnson and Son, Inc. (2001) Submission of Efficacy Data in Support of the Registration of OFF! Botanicals 1. Transmittal of 1 Study.	21-Dec-2001
45564201	Ropiak, D. (2001) Determining Repellency of Uick-2 (10% p-menthane 3,8 diol) Against Biting Gnats (commonly called no-see-ums)(Culicoides spp) and Biting Flies (Black Flies)(Simulium spp.) in the Field: Lab Project Number: 377E2: 377E1: ENT-REP-002. Unpublished study prepared by S.C. Johnson and Son, Inc. 36 p.	21-Dec-2001
45615200	S.C. Johnson & Son, Inc. (2002) Submission of Product Chemistry, Toxicity, Risk and Exposure Data in Support of the Application for Registration of UICK-T. Transmittal of 5 Studies.	26-Feb-2002

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
45615201	Kongshaug, P. (2002) Product Chemistry Data for UICK-T: Lab Project Number: 15125P71: ARTM-W-135061. Unpublished study prepared by S.C. Johnson and Son, Inc. 34 p. {OPPTS 880.1100, 880.1200, 880.1400, 830.1750, 830.1800}	26-Feb-2002
45615202	Smith, G. (2002) Physical and Chemical Characteristics of UICK-T: Lab Project Number: 15125P71: 454A2: 15125P71-A2. Unpublished study prepared by S.C. Johnson and Son, Inc. 14 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.7000, 830.6317, 830.6320}	26-Feb-2002
45615203	Bonnette, K. (2001) A Dose Response Eye Irritation Study in Rabbits with UICK-2: Amended Final Report: Lab Project Number: 3068.197: 377: 15045R59-2. Unpublished study prepared by Springborn Laboratories, Inc. 41 p. {OPPTS 870.2400}	26-Feb-2002
45615204	Bonnette, K. (2001) An Eye Irritation Study in Rabbits Using a Towelette SCJ NB# 15125P42: Final Report: Lab Project Number: 3068.220. Unpublished study prepared by Springborn Laboratories, Inc. 28 p. {OPPTS 870.2400}	26-Feb-2002
45615205	Driver, J.; Ross, J. (2002) Hazard Identification and Evaluation of Potential Exposures and Health Risks Associated with Consumer Use of p-Menthane-3,8-diol in UICK-T Insect Repellent Formulation: Lab Project Number: IS.C:01-142-02. Unpublished study prepared by infoscientific.com. Inc. 27 p.	26-Feb-2002
45650600	S.C. Johnson & Son, Inc. (2002) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Claire-1. Transmittal of 10 Studies.	10-Apr-2002
45650601	Kongshaug, P. (2002) Product Chemistry Data for Claire-1 Formula Number 15125P98-1. Unpublished study prepared by S.C. Johnson and Son, Inc. 11 p. {OPPTS 830.1750, 830.1800, 880.1000, 880.1400}	10-Apr-2002
45650602	Smith, G. (2000) Physical and Chemical Characteristics of Claire-1 Formula Number 15125P98-1: Lab Project Number: 15125P98-1-A2: 429A2: ARTM-GA-1. Unpublished study prepared by S.C. Johnson and Son, Inc. 17 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.7300, 830.6315, 830.7100, 830.6320}	10-Apr-2002
45650603	Bonnette, K. (2000) Acute Oral Toxicity Study in Rats with Claire-1: Final Report: Lab Project Number: 3068.260: 429. Unpublished study prepared by Springborn Laboratories, Inc. 27 p. {OPPTS 870.1100}	10-Apr-2002
45650604	Bonnette, K. (2000) Acute Dermal Toxicity Study in Rabbits with Claire-1: Final Report: Lab Project Number: 3068.261: 429. Unpublished study prepared by Springborn Laboratories, Inc. 34 p.	10-Apr-2002
45650605	Bonnette, K. (2000) A Primary Eye Irritation Study in Rabbits with Claire-1: Final Report: Lab Project Number: 3068.263: 429. Unpublished study prepared by Springborn Laboratories, Inc. 26 p. {OPPTS 870.2400}	10-Apr-2002
45650606	Bonnette, K. (2000) An Acute Nose-Only Inhalation Toxicity Study in Rats with Claire-1: Final Report: Lab Project Number: 3068.262: 429. Unpublished study prepared by Springborn Laboratories, Inc. 49 p. {OPPTS 870.1300}	10-Apr-2002

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
45650607	Bonnette, K. (2000) A Primary Skin Irritation Study in Rabbits with Claire-1: Final Report: Lab Project Number: 3068.264: 429. Unpublished study prepared by Springborn Laboratories, Inc. 28 p. {OPPTS 870.2500}	10-Apr-2002
45650608	Bonnette, K. (2000) A Dermal Sensitization Study in Guinea Pigs with Claire-1: Modified Buehler Design: Final Report: Lab Project Number: 3068.265: 429. Unpublished study prepared by Springborn Laboratories, Inc. 75 p. {OPPTS 870.2600}	10-Apr-2002
45650609	Ropiak, D. (2001) Determining Repellency of Claire-1 (10% p-Menthane 3.8 Diol) Against Biting Gnats (Commonly Called No-See-ums) (Culicoides spp.), Biting Flies (Black Flies) (Simulium spp.) and Mosquitoes (Culicdae) in the Field: Lab Project Number: 429: 142542: 429E1. Unpublished study prepared by S.C. Johnson and Son, Inc. 56 p.	10-Apr-2002
45650610	Ropiak, D. (2001) Determining Repellency of Claire-1 (10% p-Menthane 3.8 Diol) Against Tick (Ixodes scapularis and Amblyomma americanum Adults) in the Laboratory: Lab Project Number: 429: 142542: 1512P98-1. Unpublished study prepared by S.C. Johnson and Son, Inc. 26 p.	10-Apr-2002
45912500	S.C. Johnson & Son, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Uick-T. Transmittal of 1 Study.	21-Apr-2003
45912501	Smith, G. (2003) Twelve Month Room Temperature Storage-Stability Study for Uick-T: Lab Project Number: 15125P71-A1: 454A1: ARSP-SS-129158. Unpublished study prepared by S.C. Johnson & Son, Inc. 17 p. {OPPTS 830.6317 and 830.6320}	21-Apr-2003
45930400	S.C. Johnson & Son, Inc. (2003) Submission of Efficacy Data in Support of the Amended Registration of OFF! Botanicals 2. Transmittal of 2 Studies.	09-May-2003
45930401	Verwey, R.; Ropiak, D. (1999) Determining Repellency of Uick-3 (10% p-Menthane 3,8 diol) Against Biting Gnats (Commonly Called No-See-Ums)(Culicoides spp), Biting Flies (Black Flies)(Simulium spp.) and Mosquitoes (Culicidae) in the Field: Amended Interim Report: Lab Project Number: 390E2: ENT-REP-002: A167. Unpublished study prepared by S.C. Johnson and Son. 24 p.	09-May-2003
45930402	Verwey, R. (2000) Determining Repellency of Uick-3 (10% p-menthane 3,8 diol) Against Biting Gnats (Commonly Called No-See-Ums)(Culicoides spp), Biting Flies (Black Flies)(Simulium spp.) and Mosquitoes (Culicidae) in the Field: Interim Report: Lab Project Number: 390E2: A167. Unpublished study prepared by S.C. Johnson & Son, Inc. 31 p. {OPPTS 810.3300}	09-May-2003
45932100	S.C. Johnson and Son Inc. (2003) Submission of Toxicity Data in Support of the Application for Registration of Uick-T. Transmittal of 1 Study.	14-May-2003
45932101	Bonnette, K. (2002) An Eye Irritation Study in Rabbits Using a Towelette SCJ NB# 15125P42: Amended Final Report: Lab Project Number: 3068.220: 019. Unpublished study prepared by Springborn Laboratories, Inc. 28 p. {OPPTS 870.2400)	14-May-2003
45932200	S.C. Johnson & Son, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Uick-T. Transmittal of 1 Study.	14-May-2003

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
45932201	Kongshaug, P. (2003) Product Chemistry Data for Uick-T Formula Number 15125P71: Lab Project Number: ARTM-W-135061: ARTM-W-126607. Unpublished study prepared by S.C. Johnson and Son, Inc. 34 p. {OPPTS 830.1750, 830.1800, 880.1000, 880.1200, 880.1400}	14-May-2003
46342800	S.C. Johnson and Son, Inc. (2004) Submission of Toxicity Data in Support of the Amended Registration of Off! Botanicals 2 and UICK-T. Transmittal of 1 Study.	10-Aug-2004
46342801	Barnett, J. (2004) Percutaneous Postnatal Developmental Neurotoxicity Study of P-Menthane 3,8-Diol in Crl:CD (SD)IGS BR VAF/Plus Rats: Final Report. Project Number: 463, 610-001. Unpublished study prepared by Pathology Associates, Inc., Research Pathology Services and Consultants in Veterinary Pathology, Inc. 628 p.	10-Aug-2004
47029300	Espree Animal Products, Inc. (2007) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Aloe Herbal Horse Spray. Transmittal of 10 Studies.	11-Jan-2007
47029301	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition Source Active Ingredients. Unpublished study prepared for Espree Animal Products, Inc. 31 p.	11-Jan-2007
47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared for Espree Animal Products, Inc. 50 p.	11-Jan-2007
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	11-Jan-2007
47029305	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Oral Toxicity Up and Down Procedure in Rats. Project Number: 21101, P320/UDP. Unpublished study prepared by Product Safety Laboratories. 14 p.	11-Jan-2007
47029306	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Dermal Toxicity Study in Rats - Limit Test. Project Number: 21102, P322/RAT. Unpublished study prepared by Product Safety Laboratories. 14 p.	11-Jan-2007
47029309	Durando, J. (2006) Aloe Herbal Horse Spray: Primary Skin Irritation Study in Rabbits. Project Number: 21105, P326. Unpublished study prepared by Product Safety Laboratories. 15 p.	11-Jan-2007
47316800	Espree Animal Products, Inc. (2008) Submission of Product Chemistry Data in Support of the Registration of Aloe Herbal Horse Spray. Transmittal of 1 Study.	08-Jan-2008
47316801	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	08-Jan-2008
47934300	Intelligent Fabric Technologies (North America), Inc. (2009) Submission of Product Chemistry, Toxicity, Efficacy and Fate Data in Support of the Application for Registration of ENGUARD Mosquito Repellent Fabric. Transmittal of 6 Studies.	15-Dec-2009

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
47934301	Nestmann, E. (2009) Product Chemistry (Enguard). Unpublished study prepared by Intelligent Fabric Technologies North America, Inc. 119 p.	15-Dec-2009
47934302	Nestmann, E. (2009) Product Chemistry (Enguard). Unpublished study prepared by Intelligent Fabric Technologies North America, Inc. 59 p.	15-Dec-2009
47934303	Nestmann, E. (2009) Product Chemistry (ENGUARD). Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 78 p.	15-Dec-2009
47934304	Nestmann, E. (2009) Acute Toxicity Request for Waivers for ENGUARD Mosquito Repellent Fabric. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 110 p.	15-Dec-2009
47934305	Nestmann, E. (2009) Non-Target Organisms and Environmental Fate (ENGUARD). Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 33 p.	15-Dec-2009
47934306	Nestmann, E. (2009) Product Performance for ENGUARD Mosquito Repellent Fabric. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 57 p.	15-Dec-2009
48104100	Intelligent Fabric Technologies (North America), Inc. (2010) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Enguard Mosquito Repellent Fabric. Transmittal of 6 Studies.	21-May-2010
48104101	Nestmann, E. (2010) (Enguard Mosquito Repellent Fabric): Product Chemistry for the End Use Product. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 115 p.	21-May-2010
48104102	Nestmann, E. (2010) (Enguard Mosquito Repellent Fabric): Product Chemistry for the Technical Grade of Active Ingredient. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 69 p.	21-May-2010
48104103	Nestmann, E. (2010) (Enguard Mosquito Repellent Fabric): Product Chemistry for the Manufacturing Concentrate. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 78 p.	21-May-2010
48104104	Nestmann, E. (2010) Acute Toxicity Request for Waivers for Enguard Mosquito Repellent Fabric. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 97 p.	21-May-2010
48104105	Nestmann, E. (2010) (Enguard Mosquito Repellent Fabric): Non-Target Organisms and Environmental Fate. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 48 p.	21-May-2010
48104106	Nestmann, E. (2010) Product Performance for Enguard Mosquito Repellent Fabric. Unpublished study prepared by Intelligent Fabric Technologies (North America), Inc. 57 p.	21-May-2010
48278600	Intelligent Fabric Technologies (North America), Inc. (2010) Submission of Product Chemistry Data in Support of the Application for Registration of ENGUARD Mosquito Repellent Fabric. Transmittal of 1 Study.	28-Oct-2010

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
48278601	Woolley, A.; O'Connor, B. (2010) Incro CS Mospelar: Determination of Storage Stability. Project Number: 2860/0001. Unpublished study prepared by Harlan Laboratories, Ltd. 29 p.	28-Oct-2010
48577200	Del Cielo (2011) Submission of Efficacy Data in Support of the Application for Registration of No Mas 003. Transmittal of 1 Study.	16-Aug-2011
48577201	Carroll, S. (2011) Field Efficacy Test of a PMD and Lemongrass Oil-Based Repellent "No Mas" Against Mosquitoes. Project Number: NO/MAS/003. Unpublished study prepared by Carroll-Loye Biological Research. 411p.	16-Aug-2011
48743200	Del Cielo (2012) Submission of Efficacy Data in Support of the Amended Registration of No MAS 003. Transmittal of 1 Study.	13-Feb-2012
48743201	Carroll, S. (2012) Supplement to Study No MAS 003: Field Efficacy Test of a PMD and Lemongrass Oil-based Repellent 'No MAS' Against Mosquitoes (MRID 48577201). Project Number: NO/MAS/003. Unpublished study prepared by Carroll-Loye Biological Research. 9p.	13-Feb-2012
49467300	S.C. Johnson & Son, Inc (2014) Submission of Product Chemistry and Toxicity Data in Support of the Amended Registration of Claire-1. Transmittal of 5 Studies.	15-Sep-2014
49467301	Nekmard, F. (2014) Product Chemistry Data for Spritz 12: Formula Number 16931P140A. Unpublished study prepared by S.C. Johnson & Son, Inc. 111p.	15-Sep-2014
49467302	Tunink, A. (2013) Spritz 12: Determination of Color, Physical State, Odor, Density, pH, Viscosity, Flammability (FlashPoint), and Oxidation/Reduction and Chemical Incompatibility. Project Number: 80225, 811. Unpublished study prepared by ABC Laboratories, Inc. 47p.	15-Sep-2014
49467303	Baldi, B. (2013) Storage Stability and Corrosion Characteristics of a Test Substance: Spritz 12 in Plastic Bottle after Two Weeks at 54 Degrees C Storage: Final Report. Project Number: 811/A2, AR/S/364, 120927/2R. Unpublished study prepared by S.C. Johnson & Son, Inc. 29p.	15-Sep-2014
49467304	Lowe, C. (2013) Spritz 12: Primary Eye Irritation Sudy in Rabbits. Project Number: 37500, P324/SCJ, 130909/4D. Unpublished study prepared by Product Safety Laboratories. 36p.	15-Sep-2014
49467305	Lowe, C. (2013) Spritz 12: Primary Skin Irritation Study in Rabbits. Project Number: 37501, P326/SCJ, 130909/4D. Unpublished study prepared by Product Safety Laboratories. 32p.	15-Sep-2014
49580700	S.C. Johnson & Son, Inc. (2015) Submission of Efficacy Protocol Data in Support of the Future Registrations of S.C. Johnson Personal Mosquito Repellent Products. Transmittal of 1 Study.	02-Mar-2015
49580701	Palm, J. (2015) Protocol Submission Package for Field Testing of S.C. Johnson Personal Mosquito Repellent Products to Support Their Use of the EPA Repellency Awareness Graphic. Project Number: 90017040. Unpublished study prepared by S.C. Johnson & Son, Inc. 676p.	02-Mar-2015
49686700	i2LResearch USA, Inc. (2015) Submission of Efficacy Data in Support of Future Registration. Transmittal of 1 Study.	31-Jul-2015

Table 10. Study Information For Ingredient *011550 / 42822-86-6 / p-Menthane-3,8-diol (PMD)*

MRID	Citation	Receipt Date
49686701	Styer, K. (2015) Protocol Submission Package for Testing of S.C. Johnson Personal Tick Repellent Products to Support Their Use of the EPA Repellency Awareness Graphic. Project Number: 15/222. Unpublished study prepared by i2LResearch USA, Inc. 353p.	31-Jul-2015
Total Rows: 173		

REFERENCES

Material Safety Data Sheet (MSDS) for p-Mentha-8-thiol-3-one. 2009. Santa Cruz Biotechnology, Inc. 2145 Delaware Ave. Santa Cruz, CA. 95060.